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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/376,774	08/17/1999	YUEN KAI FUNG	D6087	6910

7590

08/25/2003

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EXAMINER

ZARA, JANE J

ART UNIT

PAPER NUMBER

1635

18

DATE MAILED: 08/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

File

Office Action Summary

Application No.

09/376,774

Applicant(s)

Fung et al

Examiner

Jane Zara

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Jun 17, 2003
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 4-28 is/are pending in the application.
- 4a) Of the above, claim(s) 4-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other: _____

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DETAILED ACTION

This Office action is in response to the communication filed June 17, 2003, Paper No. 17.

Claims 1 and 4-28 are pending in the instant application.

Election/Restriction

This application contains claims 4-28 drawn to an invention nonelected without traverse in Paper No. 5. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Response to Arguments and Amendments

Specification

The disclosure is objected to because of the following informalities: The amendment to the specification filed June 19, 2003, for inserting text onto page 38, line 12, does not seem appropriately placed. Appropriate correction is required.

Maintained Rejections

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention, for the reasons of record set forth in the Office action mailed April 22, 2003, Paper No. 16.

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Applicant's arguments filed June 17, 2003 have been fully considered but they are not persuasive. Applicants argue that because references have been cited that particularly describe the nucleotide sequence of the human heat shock 70 gene promoter (Voellmy et al), claim 1 is not unclear.

While it is true that references have been cited in the disclosure to describe the various parts of the claimed vector pDATH-X, the claim reads broadly on any previously disclosed sequences of the tetracycline repressor, the VP16 transcription activation domain and the human heat shock 70 gene promoter, not just those cited. The claimed invention cites particular amino acid numbers (i.e. aa 1-207 of a tetracycline repressor and the last 130 amino acids of a VP16 of herpes simplex virus), as well as particular nucleotide numbers (i.e. (-260 to 30 of human heat shock 70 gene promoter). But without particular accompanying and appropriate sequence identifiers, these sequences cited in the claim read on any previously reported constructs of the tet repressor, VP16 transcription activation domain or hsp 70 gene promoter, and have different corresponding sequence numbers, since all of these sequences have been reported in various ways in the prior art. Without a particular sequence identified, the metes and bounds of the claimed invention cannot be unambiguously determined from the language of the claim, and therefore the claim is still indefinite.

Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to

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which it pertains, for the reasons of record set forth in the Office action mailed April 22, 2003, Paper No. 16.

Applicant's arguments filed June 17, 2003 have been fully considered but they are not persuasive. Applicants argue that because references have been cited that particularly describe the nucleotide sequence of the human heat shock 70 gene promoter (Voellmy et al), and the other sequence numbers in the claim have been described in the instant disclosure, the claimed invention is adequately described.

Contrary to Applicants' assertions, the claimed invention reads on sequence numbers (nucleotide or amino acid numbers cited in claim 1) that may be obtained from sequences disclosed for the tet repressor, the VP16 transcription activation domain or the human heat shock 70 gene promoter from any and/or all constructs previously reported in the prior art, not just the references cited by Applicants. There is no assurance that the sequences reported in all of the prior art disclosing the tet repressor, the VP16 transcription activation domain or the human heat shock 70 gene promoter will have exactly the same corresponding amino acid or nucleotide numbers. Therefore, it would require undue experimentation to determine that the numbers of each prior art disclosure of a particular construct exactly correspond to each other. Consequently, the instant 112, first paragraph rejection is maintained for the pending claim.

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Allowable Subject Matter

The deposited pDATH-X vector appears to be free of the prior art and would be allowable if claimed without relying on the particular sequence numbers that have been delineated in the claim.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

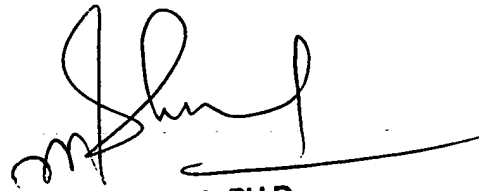
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Certain papers related to this application may be submitted to Art Unit 1635 by facsimile transmission. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). The official fax telephone numbers for the Group are (703) 308-4242 and (703) 305-3014. NOTE: If Applicant *does* submit a paper by fax, the original signed copy should be

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retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jane Zara** whose telephone number is (703) 306-5820. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached on (703) 308-0447. Any inquiry regarding this application should be directed to the patent analyst, Katrina Turner, whose telephone number is (703) 305-3413. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



RAM R. SHUKLA, PH.D.
PRIMARY EXAMINER

JZ

August 18, 2003